K090006

OCT 15 2009

510(k) Summary

SUBMITTER:

LIFEBRIDGE® Medizintechnik AG
Simon-Ohm-Str 1
84539 Ampfing Germany

CONTACT PERSON:

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Medical Device Approvals, Inc.
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DATE PREPARED:

May 5, 2009

DEVICE TRADE NAME:

LIFEBRIDGE $B_2T^®$ SYSTEM

COMMON/USUAL NAME:

Cardiopulmonary Support System

CLASSIFICATION NAMES:

Cardiopulmonary bypass heart/lung machine console (21 CFR 870.4220)
Non-roller type cardiopulmonary bypass blood pump (21 CFR 870.4360)
Cardiopulmonary bypass vascular catheter, cannulae, or tubing (21 CFR 870.4210)
Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (21 CFR 870.4290)
Cardiopulmonary bypass blood reservoir (21 CFR 870.4400)
Cardiopulmonary bypass pump speed control (21 CFR 870.4380)
Cardiopulmonary bypass oxygenator (21 CFR 870.4350)
Cardiopulmonary bypass heat exchanger (21 CFR 870.4240)
Cardiopulmonary bypass arterial line blood filter (21 CFR 870.4260)
Cardiopulmonary bypass level sensing monitor and/or control (21 CFR 870.4340)
Cardiopulmonary bypass bubble detector (21 CFR 870.4205)

PREDICATE DEVICES:

Bard (CPS) Cardiopulmonary Support System (K892664)
Medtronic Performer CPB and Resting Heart System (K031700, K052555)
Jostra MECC System (K023132)
Jostra HL-20 Integrated Perfusion System (K943803)
RotaFlow Centrifugal Pump system (K991864)

DEVICE DESCRIPTION:

The LIFEBRIDGE B_2T SYSTEM is a compact, pre-assembled, modular system consisting of:

1. Patient module housing an extracorporeal circuit comprised of several previously 510k-cleared devices. The circuit includes a rigid reservoir bag, a centrifugal pump, oxygenator, arterial filter, active air management system, tubing and connectors.

2. Sensors, including flow, pressure, level and bubble to read system parameters.

3. Control module that contains the electronics and user interface.

4. Base module that contains a touch screen, the main power connection and acts as a stable frame for the system.

The following LIFEBRIDGE B_2T SYSTEM components have been previously 510(k)-cleared for use in cardiopulmonary bypass: oxygenator, arterial filter, centrifugal pump, level sensors, and bubble detector.

INDICATIONS FOR USE:

The LIFEBRIDGE B_2T SYSTEM is indicated for use as an extracorporeal blood oxygenation system for patients needing short term, 6 hours or less, cardiac and/or pulmonary support. The device is to be operated by trained personnel under the supervision of a physician.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

The LIFEBRIDGE B_2T SYSTEM is comprised of standard cardiopulmonary bypass components packaged into a modular, user-friendly system. The technological characteristics of the device are equivalent to traditional cardiopulmonary circulatory support systems. The LIFEBRIDGE B_2T SYSTEM is substantially equivalent to the Bard (CPS) Cardiopulmonary Support System (K892664), Medtronic Performer CPB and Resting Heart System (K031700, K052555), and Jostra MECC System (K023132), in that all are indicated for use as cardiopulmonary support systems for periods up to six hours, and share equivalent technological characteristics. All of the devices incorporate previously 510(k)-cleared cardiopulmonary bypass components into a pre-assembled, optimally-sized system.

Non-clinical tests performed on the LIFEBRIDGE B_2T SYSTEM provide evidence of the safety and effectiveness of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 5 2009

LIFEBRIDGE Medizinetechnik AG
c/o Medical Device Approvals, Inc.
Ms. Kathleen Johnson
1282 Round Hill Rd.
Bryn Mawr, PA 19010

Re: K090006
Trade/Device Name: LIFEBRIDGE B_2T System
Regulation Number: 21 CFR 870.4220
Regulation Name: Console, Heart-Lung Machine, Cardiopulmonary bypass
Regulatory Class: Class II
Product Code: DTQ
Dated: October 2, 2009
Received: October 5, 2009

Dear Ms Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090006

Device Name: LIFEBRIDGE B2T System

Indications For Use:
The LIFEBRIDGE B2T System is indicated for use as an extracorporeal blood oxygenation system for patients needing short term, 6 hours or less, cardiac and/or pulmonary support.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090006